PUBLIC HEALTH CODE (EXCERPT)
Act 368 of 1978

PART 205
CLINICAL AND OTHER LABORATORIES

333.20501 Definitions; principles of construction.

Sec. 20501. (1) As used in this part:

(a) "Laboratory director" means the individual responsible for administration of the technical and scientific operation of a clinical laboratory, including the supervision of procedures and reporting of findings.

(b) "Owner" means a person who owns and controls a clinical laboratory.

(2) In addition, article 1 contains general definitions and principles of construction applicable to all articles in this code and part 201 contains definitions applicable to this part.

History: 1978, Act 368, Eff. Sept. 30, 1978.

Compiler's note: For transfer of powers and duties of the division of health facility licensing and certification in the bureau of health systems, division of federal support services, and the division of emergency medical services, with the exception of the division of managed care and division of health facility development, from the department of public health to the director of the department of commerce, see E.R.O. No. 1996-1, compiled at MCL 330.3101 of the Michigan Compiled Laws.

For transfer of powers and duties of the bureau of health services from the department of consumer and industry services to the director of the department of community health by Type II transfer, see E.R.O. No. 2003-1, compiled at MCL 445.2011.

Popular name: Act 368

333.20507 Laboratories to which MCL 333.20501 to 333.20525 inapplicable.

Sec. 20507. Sections 20501 to 20525 do not apply to any of the following:

(a) A laboratory where examinations are always performed personally by the individual desiring the information.

(b) A laboratory operated by an individual licensed to practice medicine, osteopathic medicine and surgery, dentistry, or podiatry who performs clinical laboratory tests or procedures personally or through his or her employees only as an adjunct to the treatment of the licensee's patients.

(c) A laboratory operated in the manner described in subdivision (b) by a group of not more than 5 individuals licensed to practice medicine, osteopathic medicine and surgery, dentistry, or podiatry.

(d) A laboratory operated by a college, university, or school approved by the department of education that is conducted for the training of its students, if the result of an examination performed in the clinical laboratory is not used in the diagnosis and treatment of disease.

(e) A laboratory operated by the federal government.

History: 1978, Act 368, Eff. Sept. 30, 1978.

Popular name: Act 368

333.20511 Clinical laboratory; license required; authorizing specific categories of procedures; contents of license; display of license and laboratory director's certificate of qualification; duration of license validity; biennial visits; manner of conducting licensing and inspection activities.

Sec. 20511. (1) A clinical laboratory shall be licensed under this article.

(2) A license shall authorize specific categories of procedures which the clinical laboratory may perform.

(3) A license shall contain on its face the name of the owner of the clinical laboratory, the name of the laboratory director, the categories of laboratory procedures authorized to be performed in the clinical laboratory, and the location at which the procedures may be performed.

(4) The license and laboratory director's certificate of qualification, if required, shall be displayed at all times in a prominent place in the clinical laboratory.

(5) A clinical laboratory license is valid for not more than 2 years after the date of issuance. Except where the department has entered into agreements as provided in section 20155(5), the department shall make at least biennial visits to clinical laboratories for the purposes of survey, evaluation, and consultation. The department shall conduct licensing and inspection activities in such a manner as to maximize discovery of changes in laboratory personnel and operations and to take advantage of inspections by voluntary accrediting organizations.

History: 1978, Act 368, Eff. Sept. 30, 1978;—Am. 1982, Act 474, Eff. Mar. 30, 1983.

Popular name: Act 368

333.20515 Requirements for license.

Sec. 20515. A license shall not be issued unless:

(a) The laboratory director has training, education, or experience related to the safe and competent administration of a clinical laboratory as prescribed by departmental rules.

(b) The department finds that the clinical laboratory is competently staffed, properly located and constructed, and properly equipped to perform the clinical laboratory procedures for which the license is sought.

(c) The owner agrees and the department determines that the clinical laboratory will be operated in the manner required by this article.

History: 1978, Act 368, Eff. Sept. 30, 1978.

Popular name: Act 368

333.20521 Responsibility for operation of clinical laboratory; record of specimens and procedures; analysis of test samples; reports; proficiency evaluation programs.

Sec. 20521. (1) The owner, laboratory director, and governing body of a clinical laboratory are responsible for the operation of the clinical laboratory.

(2) The laboratory director is responsible for the making and keeping of an accurate record for each specimen examined and procedure followed.

(3) A clinical laboratory shall analyze test samples submitted by the department and report to the department on the results of the analyses, except that proficiency evaluation programs of recognized professional organizations may be acceptable to the department in lieu thereof. The analyses and reports may be considered by the department in taking action under section 20165 or 20525.

History: 1978, Act 368, Eff. Sept. 30, 1978.

Popular name: Act 368

333.20525 Denial, limitation, suspension, or revocation of license; grounds.

Sec. 20525. In addition to the grounds for disciplinary action set forth in section 20165 the department may deny, limit, suspend, or revoke a license upon a finding that the owner, laboratory director, or an employee of a clinical laboratory has done any of the following:

(a) Demonstrated incompetence or consistently erred in the performance of the clinical laboratory examinations or procedures.

(b) Performed, or represented himself or herself as entitled to perform, a clinical laboratory procedure or category of procedures not authorized in the certificate of licensure.

(c) Solicited referral of specimens to the clinical laboratory by false advertising or by offering or implying, directly or indirectly, discounts, rebates, or other benefits or considerations to persons referring patients or work to the clinical laboratory.

(d) Reported on clinical laboratory work or referred samples required to be tested under section 20521 actually performed in another laboratory without stating that the work was performed there.

(e) Billed patients or third party payors for laboratory work not actually performed or not requested by the patient's physician.

History: 1978, Act 368, Eff. Sept. 30, 1978.

Popular name: Act 368

333.20531 Lead analysis; clinical laboratory reporting requirements.

Sec. 20531. Not later than 90 days after the effective date of this section, the department shall mail a notice to each clinical laboratory doing business in this state explaining the reporting requirements of this section. Beginning October 1, 2005, a clinical laboratory that analyzes a blood sample for lead shall report the results of the blood lead analysis to the department electronically in a format as prescribed by the department. The clinical laboratory shall submit the report to the department as required under this section within 5 days after the analysis is completed.

History: Add. 2004, Act 54, Imd. Eff. Apr. 12, 2004.

Popular name: Act 368

333.20551 Registration of laboratory or other place handling, cultivating, selling, giving away, or shipping pathogenic microorganisms, or doing recombinant deoxyribonucleic acid research; application for and duration of registration number; clinical laboratory considered registered; “handling,”“cultivating,”“shipping” defined.

Sec. 20551. (1) A laboratory or other place where live bacteria, fungi, mycoplasma, parasites, viruses, or other microorganisms of a pathogenic nature are handled, cultivated, sold, given away, or shipped from or to

or where recombinant deoxyribonucleic acid research is done shall be registered with the department, and a registration number shall be issued to each place registered. An application for a registration number shall be made by the person in charge of the laboratory or other place where the pathogens are handled or where recombinant deoxyribonucleic acid research is done. The registration number is valid for 1 year and may be renewed upon application to the department.

(2) A clinical laboratory licensed in microbiology under sections 20501 to 20525 is registered for purposes of this section and section 20552, and its license number shall be used as its registration number.

(3) As used in sections 20551 and 20552, "handled", "cultivated", or "shipped" does not include the collection of specimens, the initial inoculation of specimens into transport media or culture media, or the shipment to registered laboratories, but does include any additional work performed on cultivated pathogenic microorganisms or any recombinant deoxyribonucleic acid research is done.

History: 1978, Act 368, Eff. Sept. 30, 1978.

Popular name: Act 368

333.20552 Registration of laboratory, department, or school handling pathogens or doing recombinant deoxyribonucleic acid research; application for and duration of registration number.

Sec. 20552. The department shall register a laboratory or a department of a college, university, or school which is responsible for the handling, cultivating, selling, giving away, or shipping of the microorganisms described in section 20551(1) or is engaged in recombinant deoxyribonucleic acid research. The person in charge of the laboratory or department where the pathogens are handled or where recombinant deoxyribonucleic acid research is done shall apply for a registration number. The registration is valid for 1 year and may be renewed upon application.

History: 1978, Act 368, Eff. Sept. 30, 1978.

Popular name: Act 368

333.20554 Sale, gift, or other distribution of live pathogenic microorganisms and cultures or recombinant deoxyribonucleic acid materials; contents of label on container; record.

Sec. 20554. Live pathogenic bacteria, fungi, mycoplasma, parasites, viruses, or other microorganisms or cultures of the microorganisms when sold, given away, or shipped by a laboratory or other person, shall bear a label on the container showing the registration number of the laboratory or other person sending the specimens and the name and address of the person to whom sent. A laboratory or person shall not sell or convey a live pathogenic microorganism or recombinant deoxyribonucleic acid materials to any other laboratory or person in this state without permission of the department unless each is registered under section 20551 or 20552. The laboratory or person shall keep a record of each sale, gift, or other distribution of live pathogenic microorganisms and cultures or recombinant deoxyribonucleic acid materials containing the name and laboratory address of the recipient or purchaser. The record shall be at all times open to examination and copying by a representative of the department.

History: 1978, Act 368, Eff. Sept. 30, 1978.

Popular name: Act 368